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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,401	01/16/2002	Alfred Pollak	7126-2	8318

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1618

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/913,401

**Applicant(s)**

POLLAK ET AL.

**Examiner**

D. L. Jones

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 33-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **RESPONSE TO APPLICANT'S ELECTION**

1. Applicant's election with traverse of Group I (claims 1-31 and 33-49) drawn to a product, method of making the product, and uses of the product wherein the product is SEQ ID No. 1 and the metal support surface is selected from the group consisting of gold, silver, and copper; the complex forming metals are selected from the group consisting of transition, lanthanide, and actinide metals; the targeting moiety is a peptide; and the disease is an oncological disease (cancer) filed 12/1/05 is acknowledged. The traversal is on the ground(s) that the invention has unity of invention. Applicant's argument is not found persuasive for reasons of record in the office action mailed 10/26/05. The groups of invention do not contain a metal support which defines a contribution over the prior art. In addition, SEQ ID No. 1 does not define a contribution over the prior art (see the prior art rejection below). In addition, the targeting moiety and ligand combinations which are conjugated to the metal support vary extensively and when taken as a whole result in vastly different complexes. Also, the diseases which the complexes may be used vary extensively. For example, the complexes may be used for assessing the severity of oncological diseases, neurological diseases, inflammatory disease, and infections. Also, the disease may be assessed using various possible methods including positron emission tomography, nuclear magnetic resonance imaging, scintigraphy, single photon emission computed tomography, perfusion contrast echocardiography, ultrafast x-ray computed tomography, and digital subtraction angiography. As a result, unity of invention is

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considered to be lacking and the restriction requirement is still deemed proper and is therefore made FINAL.

**Note:** Claims 1-31 and 33-49 will only be examined to the extent that they read on the elected invention.

## COMMENT

2. Claims 1-31 and 33-49 are pending.

## 103 REJECTION

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-31 and 33-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al (US Patent No. 6,921,526).

**Hoffman et al** disclose gastrin receptor avid peptide conjugates that are useful for treating or diagnosing neoplastic diseases (see entire document, especially, abstract; column 3, lines 25-30; column 4, lines 35-36 and 50-54; column 9, lines 20-25). In Figure 22, a complex is disclose having a chelator, metal, linker moiety, and Applicant's SEQ ID No. 1 (QWAVGHLM). The metals complexing group or moiety is a chelating agent or chelator which complexes to metals such as Rh, Re, Tc, Sm, Ho, Y,

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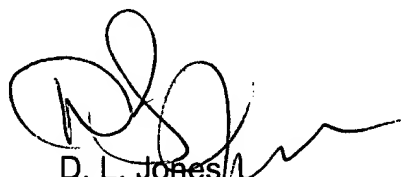
or Au. The chelating agent is attached to or bound to the gastrin releasing peptide (GRP) agonist binding region to produce a conjugate that retains its capability for high affinity and specific binding to GRP receptors (column 5, lines 6-13). The unit dose utilized is dependent upon the distribution profile of the chosen conjugate in the sense that a rapidly cleared conjugate may be administered in higher doses than one that clears less rapidly. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a composition comprising Applicant's SEQ ID No. 1, a metal support, and a ligand as set forth in independent claim 1 for use with oncological disease because Hoffman et al disclose a metal complex comprising SEQ ID No. 1 having a metal, chelator, linker and targeting moiety (SEQ ID No. 1) wherein the complexes may be used as therapeutic and imaging agent for cancer cells. In addition, a skilled practitioner in the art would recognize that depending on what radionuclide is utilized, the method of detection would vary.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones  
Primary Examiner  
Art Unit 1618

March 6, 2006